

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Endocrinologic and Metabolic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 25, 26, and 27, 2002, from 8 a.m. to 5 p.m.

*Location:* Hilton, The Ballroom, 8727 Colesville Rd., Silver Spring, MD.

*Contact Person:* Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX 301-827-6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On September 25, 2002, the committee will discuss appropriate designs for clinical trials of new osteoporosis treatments. On September 26,

2002, the committee will discuss the safety and efficacy of biologic licensing application BL 103979, FABRAZYME (agalsidase beta, Genzyme Corp.) for the treatment of Fabry's disease. On September 27, 2002, the committee will discuss the safety and efficacy of biologic licensing application BL 103977, REPLAGAL (agalsidase alfa, Transkaryotic Therapies) for the treatment of Fabry's disease.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 17, 2002. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 17, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated: July 22, 2002.

**Linda Arey Skladany,**

*Senior Associate Commissioner for External Relations.*

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